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No. 85-619

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1985

MERRELL DOW PHARMACEUTICALS INC.,
Petitioner,

vs.

LARRY JAMES CHRISTOPHER THOMPSON AND DONNA LYNN THOMPSON AS NEXT FRIENDS AND GUARDIANS OF JESSICA ELIZABETH THOMPSON, LARRY JAMES CHRISTOPHER THOMPSON, INDIVIDUALLY AND DONNA LYNN THOMPSON, INDIVIDUALLY, *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF FOR PETITIONER

REVIEW OF PETITIONER'S CONTENTIONS

To reply to Respondents' arguments, it is first necessary to clarify what rulings the Petitioner seeks from this Court and what rulings it does not seek. Petitioner's analysis poses two questions. First, does the Respondents' allegation that Petitioner violated the Food, Drug and Cosmetic Act by "misbranding" drugs through misleading promotion of those

drugs render the Fourth Cause of Action one "necessarily dependent" for its resolution on decision of a substantial issue of federal law? Second, if the first question be answered in the affirmative, does the fact that the Respondents also pled other purely non-federal grounds for recovery for the same injuries deprive the district court of jurisdiction over the "federal question" claims asserted in their Fourth Causes of Action?

Petitioner urges that a claim which necessarily depends on a finding that the defendant violated federal law confers federal question jurisdiction under 28 U.S.C. § 1331, if the claim is such that interpretation and construction of federal law will be necessary to the decision of that claim.[1] Petitioner also urges that if a claim is, in this fashion, necessarily dependent on a federal legal interpretation, it is of no significance that a plaintiff has pled parallel claims for the same injuries which do not depend upon federal law for their decision.

Contrary to the Respondents' implication, Petitioner does not urge that federal jurisdiction is present in *any* situation in which a plaintiff brings a non-federally created claim which invokes federal law or which might rely upon federal law. Petitioner's jurisdictional contention is limited, rather, to a situation in which interpretation and construction of federal

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[1] Respondents cannot deny that their Fourth Causes of Action allege injuries proximately resulting from the federal violations which they allege. Both courts below accepted without inquiry Respondents' post-removal "concession" that they had no right to a private claim under the Food, Drug and Cosmetic Act. Though they deny any attempt to state a private cause of action under the Food, Drug and Cosmetic Act, Respondents included all elements of such a claim in their pleadings. A reading of the complaints suggests that their mention of a "rebuttable presumption of negligence" was not the gist of their Fourth Causes of Action at all, but merely a gratuitous cross-reference to their First Causes of Action. Had the Respondents been desirous of "federal question" jurisdiction, they need only have added to their complaints an invocation of 28 U.S.C. § 1331. Petitioner's arguments on this independent ground for federal jurisdiction are set forth at pages 36 and 37 of its principal brief and will not be repeated here.

law will obviously be necessary to the determination of the plaintiff's claim. The Petitioner does not impugn the competence of the state courts in *applying* federal law but asks this Court to recognize that concurrent original federal jurisdiction is present where a case requires the *development* of federal law through the construction and interpretation of federal statutes. Where, as here, an interpretation that the statute applies to foreign claims will be prerequisite to a decision to apply it, the application of the statute and its "construction" are synonomous.

ARGUMENT

I. RESPONDENTS' SUCCESSFUL PROSECUTION OF THEIR FOURTH CAUSES OF ACTION WILL REQUIRE ADOPTION OF A NOVEL AND EXPANDED VIEW OF THE TERRITORIAL APPLICATION OF THE FOOD, DRUG AND COSMETIC ACT.

Respondents avoid comment on the history of the mass tort litigation involving the American drug Bendectin, its Canadian counterpart of the same name, and the similar British drug "Debendox." Yet, this history explains the novelty of the Respondents' contentions and the reasons why these claims were pled as they were. As Respondents do not dispute, their counsel appeared on behalf of other Canadian and British plaintiffs who previously brought actions in the Southern District of Ohio against the Petitioner. These earlier plaintiffs also attributed their children's birth defects to Debendox and Canadian Bendectin. Their cases were dismissed by the district court on grounds of *forum non conveniens*. Chief among the reasons for these dismissals were that the plaintiffs and their injuries were of foreign origin and that foreign law would likely control the outcome. *In re Richardson-Merrell, Inc.*, 545 F. Supp. 1130 (S.D. Ohio 1982), *aff'd sub. nom. Dowling* v. *Richardson-Merrell, Inc.*, 727 F.2d 608 (6th Cir. 1984); *Vandervliet* v. *Richardson-Merrell, Inc.*, Case No.

C-1-82-470, Order Granting Defendant's Motion to Dismiss on *Forum Non Conveniens* Grounds and Judgment of Dismissal (S.D. Ohio Apr. 13, 1984).

The advantages of an American forum to Respondents are discussed at length in the memoranda filed by the parties below concerning the *forum non conveniens* issue. These memoranda are part of the record of this case. Original federal jurisdiction was available to the Respondents by reason of diversity of citizenship,[2] but they wished to avoid the dismissal on grounds of *forum non conveniens* which would certainly ensue if they filed in federal court. Accordingly, they filed their suits in state court, but took the additional step of implying that the drug which they accused of causing their injuries was American Bendectin, rather than Debendox or Canadian Bendectin. This operated to obscure the name and origin of the drugs which were actually available to the Respondent mothers and which they allegedly took. In their complaints, Respondents treated the name "Bendectin" as a generic name and were, thus, able to identify the drug which Mrs. MacTavish actually claims to have taken as "Bendectin," even though the name the British drug actually bore was "Debendox."

The name "Bendectin" is not, however, a generic name but a *brand name*, belonging to *two* products, each licensed and regulated by a different sovereign. One "Bendectin" is the American drug, made and sold in the United States under the

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[2] Because of the Respondents' alien citizenship and the amount in controversy, these cases were within the original jurisdiction of the district court under 28 U.S.C. § 1332(a)(2). However, this was not a proper basis for removal due to Petitioner's forum state citizenship. 28 U.S.C. § 1441(b). In such a case, this Court has ruled that improper removal is a waivable (and, hence, a *non-jurisdictional*) defect. *Grubbs* v. *General Electric Credit Corp.*, 405 U.S. 699 (1972). Even under the court of appeal's conclusion, herein disputed, that "federal question" jurisdiction was lacking, it erred in assuming, per 28 U.S.C. § 1447(c), that the Respondents' cases had been "removed improvidently *and without jurisdiction*." (Emphasis added.) If "federal question" jurisdiction is unavailable, the suits *were* removed "improvidently" but the district court was *not* "without jurisdiction."

jurisdiction of the Food and Drug Administration, and the other "Bendectin" a drug made and sold in Canada under the governmental regulation of that country. "Debendox" is a distinct brand name pertinent to a drug manufactured in the United Kingdom by a British manufacturer and sold there by a subsidiary of the Petitioner.[3] The distinction between these brands of American and foreign drugs and the corporate separateness and differing nationalities of the concerns which produced and sold them, were obvious obstacles to the Respondents' plan to secure the benefits of an American forum and to participate in the American "Bendectin" litigation.

Mindful of the dismissal for *forum non conveniens* of virtually identical Scottish and Canadian claims, Respondents inaccurately asserted in their complaints that they had taken American Bendectin. After removal, in opposing dismissal on the basis of *forum non conveniens* and seeking remand, the Respondents disclosed to the court that they had taken "Debendox."[4] (Joint Appendix at 43.) Respondents added:

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[3] Respondents note that, historically, there was occasional shipment of bulk drug from the United States to the United Kingdom to cover shortfalls in the local production of Debendox. This ceased in 1977 and Mrs. MacTavish's pregnancy did not begin until August 1978. The *MacTavish* Respondents have not attempted to demonstrate that Mrs. MacTavish took an American-made drug. In any case, it is "misbranding" of Debendox which is the federal violation at issue. If Mrs. MacTavish took a "misbranded" drug, it was misbranded in the United Kingdom and the relevance of U.S. law to the labeling and promotion of drugs in the U.K. for sale in the U.K. is still the issue of her claims.

[4] Of course, *a* Canadian drug named "Bendectin" was available to Mrs. Thompson in Canada. The Thompson complaint, however, treated the Canadian drug as American-made. But, in litigating the issue of *forum non conveniens*, Petitioner demonstrated by affidavit that Debendox and Canadian Bendectin were manufactured and "branded" in the United Kingdom and Canada and no contrary evidence was offered by Respondents. Apart from Respondents' misleading complaints, there is no contention or evidence in the record that the Debendox or "Bendectin" available to Respondents were made, promoted or "branded" in this country.

"Debendox is the British trade name for the anti-nausea morning sickness drug Bendectin manufactured by defendant Merrill [sic]." The clear implication of this statement is that Debendox, itself, was manufactured in the United States. However, this Court will search the record in vain for any direct assertion by the Respondents that the Debendox available to the U.K. Respondent, Mrs. MacTavish, was manufactured in the United States.

Once again, the verbal feint in which the Respondents engaged has to be appreciated. Debendox is a drug made in the United Kingdom by an unrelated British concern and sold there by the Petitioner's subsidiary. *Dowling* v. *Richardson-Merrell, Inc.*, 727 F.2d 608, 611 (6th Cir. 1984). This fact was well known to the Respondents since their counsel argued before the Sixth Circuit for the plaintiff/appellants in the *Dowling* cases three months after Respondents' complaints were filed. 727 F.2d at 609. The foreign origin of Debendox was undisputed in the *Dowling* cases. Debendox was (at times) of the same formulation as Bendectin and was marketed in the United Kingdom beginning in 1958.

It is undisputed that the Petitioner developed, tested and promoted American Bendectin in the United States and that the Canadian and British drugs are sold by Petitioners' related corporations in the foreign countries of their origin. However, there is no assertion in the record that the Canadian or British drugs were themselves promoted or "branded" in the United States. Clearly they were not sold here.

It is the British and Canadian (as well as American) drugs which the Petitioner is accused of "misbranding" in violation of the Food, Drug and Cosmetic Act.[5] Stripped of its semantic

[5] It was only in their motion to remand that Respondents acknowledged that their "misbranding" allegation pertained, not only to the drug available in the United States, but also to the foreign drugs available in their homelands. (J.A. at 44) If the drugs which Respondents claim to have taken were not "misbranded," they would have no standing to complain of the "misbranding" of drugs sold in this country.

camouflage, this is the contention which underlies the Fourth Cause of Action of each complaint, one which the Respondents contend is irrelevant to federal question jurisdiction.

Whether the Congress ordained that the Food, Drug and Cosmetic Act govern the "branding" of drugs which are sold in foreign countries is a federal legal question of great significance. Respondents effectively contend that this issue should be decided anew by each state court which tries a case brought by a foreign plaintiff who claims injury from a violation of such statute. Such state court decisions would go beyond the application of settled federal law and will break new ground of statutory interpretation.

II. STATE COURT DECISIONS ON THE MEANING AND EXTRATERRITORIAL SCOPE OF THE FOOD, DRUG AND COSMETIC ACT WOULD EVADE THE ABILITY OF THIS COURT TO IMPOSE UNIFORMITY OF FEDERAL INTERPRETATION.

The Respondents do not dispute that, to prevail on their Fourth Cause of Action, they must demonstrate that the Petitioner violated the Food, Drug and Cosmetic Act by "misbranding" Canadian Bendectin and Debendox. They do not critique or even address the Petitioners' analysis of the elements of proof inherent in their accusation of the "misbranding" of these drugs. However, they seemingly dispute that their Fourth Causes of Action will require construction and interpretation of the Food, Drug and Cosmetic Act. Respondents contend that the issue whether the British and Canadian drugs violated federal law may be submitted to a state court *jury* without any interpretative instruction by the trial court. Say the Respondents: "In effect, all the court must do is to command the jury to determine whether the particular regulations at issue have been violated and, if so, whether the plaintiff's injuries are of the type which the regulation intended to avoid." (Respondents' Brief at 38.)

This argument of the Respondents is, in reality, the best argument for original federal jurisdiction over a claim of this kind.

In the Respondents' view, not even the state court itself, but, rather, *the jury*, must deliberate the purposes of the Food, Drug and Cosmetic Act, determine its *applicability* to foreign plaintiffs (and foreign drugs), evaluate the advertising and promotional program of Petitioner for compliance with the federal statute and regulations, and emerge with a verdict. Respondents do not attempt to reconcile this proposition with their argument that "the availability of review by this Court on *certiorari* is sufficient to protect the federal interest involved." (Respondents' Brief at 27.) They do not explain the manner in which this Court (or any court) could review and correct the jury room deliberations of each state court jury on the meaning and scope of this federal regulatory statute. Even the Common Pleas Court of Hamilton County, Ohio (where Respondents' cases originated), would have no means to impose local uniformity on the several juries which would hear cases of this type. The jurors themselves, were they aware of the concept of *stare decisis*, would have no means to know how other juries had interpreted the statute, and no way to follow such a "precedent," even were they so inclined. Every such decision of a jury would be *ad hoc*, and unburdened by what had come before. This may be the chief virtue, from Respondents' viewpoint, of a state forum.

Petitioner disagrees that a state court could submit the issue of claimed Food, Drug and Cosmetic Act violations to a jury without an initial judicial construction of the statute, that construction then to be applied to the facts as the jury finds them. A claim of negligence *per se* does not, as Respondents contend, merely pose a discretionary decision on whether the state should "borrow" a federal safety standard. The substantive law of the controlling jurisdiction determines what effect, if any, a statutory violation has on tort liability. This is not an *ad hoc* determination of the court or jury but the standing rule of law of the place whose law controls.[6]

[6] In the *Dowling* cases, the district court observed: "At this juncture, then, it appears virtually certain that the substantive law of the United Kingdom will govern the actions." 545 F. Supp. at 1136. *See also Vandervliet* v. *Richardson-Merrell, Inc.*, Case No. C-1-82-470, Order Granting Defendant's Motion to Dismiss on *Forum Non Conveniens* grounds (S.D. Ohio Apr. 13, 1984) re application of Canadian law.

However, the legal questions as to the statute's requirements (or even whether it pertains) are always governed by the law which gives the statute its force, in this case, that of the United States. Here, the federal legal questions are (1) does the statute even govern the alleged injurious actions of the Petitioner, the "misbranding" of drugs in foreign countries, (2) did Petitioner's actions violate the statute and (3) are Respondents among those whom the law was designed to protect. Whatever use the state court may make of the answers, the *questions* are federal.

III. SUSTAINING "FEDERAL QUESTION JURISDICTION" OVER RESPONDENTS' CLAIMS WILL ONLY RECOGNIZE FEDERAL JURISDICTION OVER NON-FEDERALLY CREATED CLAIMS WHICH SHOW THE NECESSITY FOR CONSTRUCTION AND INTERPRETATION OF FEDERAL LAW.

In closing their brief, Respondents argue that recognition of federal jurisdiction over their claims will extend that jurisdiction to every non-federally created claim which requires for its adjudication the *application* of federal law. This is a pretended issue which ignores the important distinction between claims which merely rely upon federal law and call for the application of such law to disputed facts, and those which will require *construction and interpretation* of federal law. The former type of case is common; the latter is not.

In *Franchise Tax Board* v. *Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), this Court acknowledged that federal jurisdiction over a claim not federally created would lie only where the resolution of such claim requires a decision on a *federal legal controversy:*

> As an initial proposition, then, the 'law that creates the cause of action' is state law, and original federal jurisdiction is unavailable unless it appears that some substantial disputed question of federal law is a necessary element of one of the well-pleaded state claims, or that one or the other claim is "really" one of federal law.
>
> Even though state law creates appellant's causes of action, its case might still 'arise under' the laws of the United States if a well-pleaded complaint established that its right to relief under state law requires resolution *of a substantial question of federal law in dispute between the parties.*

463 U.S. at 13 (emphasis added).

The distinction between a federal legal controversy and a merely factual dispute to be governed by federal law is a crucial one which Respondents' "flood of litigation" argument completely neglects. Only an unusual case will present a claim which, though not federally created, requires resolution of a federal *legal* question.

Complaints are drafted to avoid the impression that the legal premise relied upon is novel or complex or would require an extension or modification of previous interpretation. Plaintiffs do not knowingly telegraph crucial legal issues to their opponents or to the court in their pleadings. Respondents' complaints illustrate this practice by blaming American Bendectin for injuries which they actually attribute to two foreign drugs. Whether this type of effort to avoid federal jurisdiction is entitled to achieve its goal is a distinct question, however. Most plaintiffs who desire a state forum can avoid overt reliance on a questionable federal legal proposition without such artifice. The best illustration of this fact is found in the numerous federal cases cited by both Petitioner and Respondents which discuss federal jurisdiction over non-federal negligence claims premised on federal safety violations.

These cases include *Moore* v. *Chesapeake & Ohio Ry. Co.*, 291 U.S. 205 (1934); *Crane* v. *Cedar Rapids & Iowa City Ry.*

Co., 395 U.S. 164 (1969); *Andersen* v. *Bingham & G. Ry. Co.*, 169 F.2d 328 (10th Cir., 1948); *Boncek* v. *Pennsylvania Ry. Co.*, 105 F. Supp. 700 (D.N.J. 1952); *Dennis* v. *Southeastern Aviation, Inc.*, 176 F. Supp. 542 (E.D. Tenn. 1959); *Jacobson* v. *New York, N.H.& H.R. Co.*, 206 F.2d 153 (1st Cir.), *cert. granted*, 346 U.S. 895 (1953) (solely on the question of diversity jurisdiction), *aff'd per curiam*, 347 U.S. 909 (1954); and *Owens* v. *New York Central R.R. Co.*, 267 F. Supp. 252 (E.D. Ill. 1967).

As Petitioner acknowledges in its principal brief, these precedents found federal jurisdiction lacking over state-created claims premised on certain federal safety violations. However, none of the opinions identified a federal legal controversy, apparent from the complaint, upon the resolution of which any particular claim would depend. *Moore*, *Crane*, *Jacobson*, *Andersen* and *Owens* each involved negligence claims based on violations of the Safety Appliance Act, a prosaic statute which left little room (and certainly posed no obvious need) for judicial construction.[7] The Tenth Circuit in *Andersen* specifically relied upon the absence of an apparent legal controversy concerning the federal statute in denying jurisdiction.

Of course, every claim has some *potential* to turn on a federal legal issue, particularly if federal law is relied upon in a complaint. This is not enough to invoke federal original jurisdiction. It will be an unusual case in which the complaint

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[7] Petitioners disagree with Respondents' contention that these courts engaged in a "balancing" of state and federal interests. Rather, all found "federal question" jurisdiction lacking over a state law claim because it was not federally created. They applied the "Holmes test" for "federal question" jurisdiction as a principle of exclusion. This was not necessarily because they were unmindful that a state-created claim could, nonetheless, "arise under" federal law, but because those state claims did not present a *federal legal controversy* requiring decision. Respondents, in fact, subtly ask this Court to validate the Holmes test as exclusive, stating: "When no federal right of action exists, issues bearing on the plaintiff's right to recover on such claims are important state concerns which should be left to be enforced by the state." R.B. at 30.

shows that plaintiff's claim depends on a favorable *interpretation* of federal law rather than its mere application.

The recognition of "federal question" jurisdiction over claims not federally created in *Franchise Tax Board* is not at odds with the cases relied upon by the Respondents. None of such cases even considers that a state-created claim might sustain "federal question jurisdiction," presumably because the facts and pleadings did not suggest the necessity of federal statutory interpretation in trial of these state-created claims.[8]

Respondents erect a strawman in warning that, under Petitioner's jurisdictional test, a complaint which *might* have relied upon a federal violation in support of a claim of negligence but did not explicitly plead the federal violation, would become removable because of that *potential* federal issue. Petitioner has never made such an argument and the "well-pleaded complaint" rule would deprive it of any validity. A complaint which does not explicitly rely on federal law cannot be a basis for federal question jurisdiction.[9]

[8] Respondents erroneously imply that the plaintiffs in *Guthrie* v. *Alabama By-Products Co.*, 328 F. Supp. 1140 (N.D. Ala. 1971), *aff'd per curiam*, 456 F.2d 1294 (5th Cir. 1972), *cert. denied*, 410 U.S. 946, *reh'g denied*, 411 U.S. 910 (1973), had argued that a state-created claim was necessarily dependent on the federal violation which they alleged. (R.B. at 21.) The plaintiffs in *Guthrie* relied solely on the premise of an implied and *federally-created* cause of action under the federal act in issue. The courts in *Guthrie* did not consider under what conditions a claim not federally created could "arise under" federal law nor did they anticipate this Court's analysis of this issue in *Franchise Tax Board*. In contrast, *Westmoreland Hospital Association* v. *Blue Cross*, 605 F.2d 119 (3d Cir. 1979), *cert. denied*, 444 U.S. 1077 (1980), discussed in Petitioner's initial brief at pages 42, 43, and 44, addresses precisely the instant questions.

[9] The only exception to this rule (and one not applicable here) is where the factual substance of a plaintiff's claim places it within an area preempted by federal law, such that the *only* available cause of action must be a federal one. As this Court noted in *Franchise Tax Board*, "a plaintiff may not defeat removal by omitting to plead necessary federal questions in a complaint. . . ." 463 U.S. at 22. Had Respondents refrained from *pleading* the federal violation, their cases would not have been removed to federal

IV. BECAUSE RESPONDENTS' FOURTH CAUSES OF ACTION NECESSARILY TURNED ON A FAVORABLE CONSTRUCTION OF THE FOOD, DRUG AND COSMETIC ACT, "FEDERAL QUESTION" JURISDICTION OBTAINED AS TO THEIR ENTIRE LAWSUITS. IT IS IRRELEVANT THAT RESPONDENTS ALSO ALLEGED ALTERNATE THEORIES OF RECOVERY WHICH WOULD NOT REQUIRE INTERPRETATION OF FEDERAL LAW.

The parties agree that Respondents cannot recover on their Fourth Causes of Action without demonstrating that the Petitioner "misbranded" Debendox and Canadian Bendectin in violation of the Food, Drug and Cosmetic Act. They also agree that Respondents' oth causes of action are not dependent on any construction of federal law. Finally, they agree that the court of appeals considered the First and Fourth Causes of Action collectively and ruled that the possibility that Respondents might recover for "negligence" on their First Cause of Action precluded federal question jurisdiction over their cases. The parties are, however, directly opposed on the proper jurisdictional significance of the other causes of action which do not invoke federal law.

Respondents and Petitioner concur that the decision of this Court in *Franchise Tax Board* v. *Construction Laborers Vacation Trust*, 463 U.S. 1 (1983), must be dispositive, but they disagree as to the meaning of that decision. Respondents focus, as did the court of appeals, on their potential for recovery for "negligence" on their First Cause of Action which did not invoke federal law. Though they also dispute the sufficiency of the federal issues inherent in the Fourth Cause of Action to sustain jurisdiction, Respondents maintain that, in any case, such federal issues are not necessary to their "right to relief." The parties, therefore, call upon this Court

court. The hypothetical case where no federal issue is pled has no relevance whatever to the instant situation.

to decide in what sense a federal issue must be "necessary" or "essential" to a plaintiff's case in order to render that case one "arising under" federal law.

For reasons unknown, neither the court of appeals nor the Respondents point out the potential for recovery on their claims for strict liability, breach of warranty or "fraud and deceit upon the consuming public . . ." (J.A. at 23, 33). If the First Cause of Action renders the federal violations "non-essential," all the other concededly non-federal[10] claims do so as well. All allege the same injuries and, thus, in the broadest sense, all concern the same "cause of action," and the same "right to relief." If the Respondents' position be adopted by this Court, a plaintiff may pose even the most difficult, novel or important federal questions in a claim which will require their resolution, and yet anchor his lawsuit firmly to the state court merely by pleading alternate grounds for recovery which do not require such resolution.

Respondents cite to this Court's decision in *Smith* v. *Kansas City Title & Trust Co.*, 255 U.S. 180 (1920), and distinguish it from their cases on the ground that the plaintiff therein relied solely on his allegation that the congressional acts in issue were unconstitutional, raising no non-federal ground for relief. The acid test of this distinction is to postulate a parallel state ground for relief in the *Smith* case and examine the result which the Respondents' legal proposition would produce. Had the plaintiff in *Smith* also pled some non-federal ground to enjoin the investment in farm loan bonds, his claim, say Respondents, would be beyond federal original jurisdiction. Adoption of the Respondents' position in this hypothetical case would confer *exclusive* original jurisdiction on the state court to adjudicate the federal constitutionality of an act of Congress. This bizarre result would proceed from the plaintiff's decision, not to refrain from reliance on federal

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[10] Petitioner does *not* concede that these claims are "state-created" claims. Their dismissal on grounds of *forum non conveniens* presupposed that United Kingdom and Canadian law would control.

late, but that he would also rely on state law. It is illogical that federal question jurisdiction be extinguished by the parallel pleading of non-federal grounds for relief.

Petitioner, in its principal brief, recalled this Court's several pronouncements in *Franchise Tax Board* which paraphrased the elements of "federal question" jurisdiction over claims not federally created. The court of appeals fixed upon the language which declared that such jurisdiction required that the substantial federal issue be an "essential" and "necessary" element of plaintiff's "cause of action" or his "right to relief." However, the court of appeals overlooked the explicit acknowledgement of this Court that such a "federally dependent" state law claim could confer subject matter jurisdiction *though other state law claims were also pled*. This Court stated:

> As an initial proposition, then, the "law that creates the cause of action" is state law and original federal jurisdiction is unavailable unless it appears that some substantial, disputed question of federal law is a necessary element of *one* of the well-pleaded state *claims*, or that *one or the other claim* is "really one of federal law."

463 U.S. at 13 (emphasis added).

This Court used the same disjunctive analysis of the causes of actions in specifically addressing the complaint at issue in *Franchise Tax Board*:

> Simply to state these principles is not to apply them to the case at hand. Appellants Complaint sets forth two "causes of action," one of which expressly refers to ERISA; if *either comes within the original jurisdiction of the federal courts, removal was proper as to the whole case.*

463 U.S. at 13 (emphasis added).

In seeking to distinguish this Court's individualized treatment of the causes of action in *Franchise Tax Board*,

Respondents confuse this Court's usage of the phrase "cause of action" and "right to relief" in *Franchise Tax Board* with the definition of "cause of action" applied in *Baltimore SS Co.* v. *Phillips*, 274 U.S. 316 (1926), with reference to the doctrine of *res judicata*. *Baltimore* v. *Phillips* defined "cause of action" as the general right to relief for a single injury, regardless of the multiplicity of legal theories or factual allegations which might support that "cause of action." By that definition, *Franchise Tax Board* presented *three* causes of action, one for each of the unpaid tax levies. By the same analysis, Respondents' complaints each present three "causes of action," i.e., one for each parent and child. Clearly, *Franchise Tax Board* used "cause of action" to mean something other than "actionable injury." In a jurisdictional decision, headings placed on pleadings and broad textbook classifications of tort theories such as "negligence" are of little use in determining whether a "cause of action" has the necessary "federal" character. The question must always be whether the plaintiff has relied upon federal law as a distinct basis for recovery so that the federal legal questions will actually be litigated by the parties.

Franchise Tax Board recognized that claims based purely on non-federal law were subject to pendent federal jurisdiction if joined with factually related claims as to which "federal question" jurisdiction exists. This recognition was extended to *any* type of claim arising under federal law, whether because federally created *or* because of an essential federal element.

In *United Mine Workers* v. *Gibbs*, 383 U.S. 715 (1966), this Court noted the error of limiting pendent jurisdiction based on an outmoded concept of "cause of action":

> This limited approach is unnecessarily grudging. Pendent jurisdiction, in the sense of judicial *power*, exists whenever there is a claim "arising under [the] Constitution, the Laws of the United States, and Treaties made, or which shall be made, under their Authority . . .," U.S. Const., Art. III, ¶ 2, and the relationship between

> that claim and the state claim permits the conclusion that the entire action before the court comprises but one constitutional "case." The federal claim must have substance sufficient to confer subject matter jurisdiction on the court. *Levering & Garrigues Co.* v. *Morrin*, 289 U.S. 103. The state and federal claims must derive from a common nucleus of operative fact. *But if, considered without regard to their federal or state character, a plaintiff's claims are such that he would ordinarily be expected to try them all in one judicial proceeding, then, assuming substantiality of the federal issues, there is power in federal courts to hear the whole.*

383 U.S. at 725 (emphasis added).

The court of appeals read *Franchise Tax Board* as excluding a claim which is dependent on an essential federal issue from this rule of law because the potential for recovery on other non-federal claims renders the federal issue non-essential. It overlooked the principle that a claim may be "federal," though not federally created. Respondents' Fourth Causes of Action are "federal claims." Their non-federal claims do not destroy this jurisdictional foundation but are rather subject to the federal jurisdiction so founded.

V. THERE IS A SUBSTANTIAL FEDERAL INTEREST IN SECURING THE UNIFORM INTERPRETATION OF THE FOOD, DRUG AND COSMETIC ACT AND IN LIMITING THE ACT'S PROHIBITIONS TO THOSE WHICH THE CONGRESS INTENDED.

Respondents assert that the application of the Food, Drug and Cosmetic Act by an Ohio court is a matter of chiefly local concern which will not impede the regulatory functions of the Food and Drug Administration. This erroneously assumes that the legislative intent behind a federal statute cannot be frustrated by an overly expansive interpretation of its provisions. It is true that a state may enact *local laws* which are

more restrictive than their federal counterparts in regulating the pharmaceutical industry. Such local laws, however, do not attempt to govern conduct beyond the borders of the state which enacts them. In contrast, state court judgments founded on claims of federal violations will impact the regulated industry beyond the borders of the forum state. When such judgments concern nationally or internationally marketed products, every plaintiff's recovery is a clarion call to other plaintiffs to sue on similar grounds. The call is nationwide and world-wide. This Court's writ of certiorari cannot, as a practical matter, tuck the bugle call back into the bugle. This nationwide impact of a federal law is a matter of proper federal concern.

In arguing the legislative history of the Food, Drug and Cosmetic Act, Respondents overlook the fact that a provision for a private right of action, expressly included in an earlier version of the bill, was omitted out of congressional concern that existing state defenses for drug product liability *would be curtailed* by such an enactment.[11] The Hearings on Senate Bill 1944 (74th Congress) produced opposition to a provision in the pending bill creating a private right of action for violations. Among the arguments advanced was the fear that such provision would curtail previously available state law defenses to such claims. Secretary of Agriculture Wallace stated:

> Why, therefore, encumber a United States statute with such a provision when an injured party already possesses an adequate remedy which can be pursued in the state courts?

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[11] Respondents egregiously mischaracterize their Fourth Causes of Action in asserting that they rely upon the alleged federal violation only in anticipation of Petitioner's defenses. Unless they prove the federal violations which they allege, Respondents' Fourth Causes of Action would be disposed of by directed verdict at the conclusion of Plaintiffs' case. Obviously, the federal violations are an essential part of Respondents' *case-in-chief*. This is why the Respondents devoted a separate section of their complaints to such violations.

> The new provision, if enacted, would only be an invitation to blackmailing claims and suits.
>
> At common law the defendant in a damage suit would have the right to plead contributory negligence and to show that the injury complained of was due primarily to the negligence of the plaintiff. That he would have such right of defense under this bill, if enacted, is not entirely certain.

Foods, Drugs and Cosmetics; Hearings on S. 1944 Before A Subcommittee of the Committee on Commerce, U.S. Senate, 74th Cong., 2nd Sess. (1933), Statement of Henry A. Wallace, Secretary of Agriculture.

The Food, Drug and Cosmetic Act is, through its regulatory provisions, a restraint on commerce. It is as much an objective of the Act to *define* that restraint as to enforce it. Though state law may properly attach local tort law consequences to federal violations, the objectives of Congress may be as readily thwarted by a state court's erroneous expansion of the Act's prohibitions, as by a drug company's violation of them.[12]

The American pharmaceutical industry is the most exposed, by its nature, to the risk of a stampede of product liability lawsuits, with the profoundly adverse financial consequences *apart from liability* which comes with such a stampede. It is as important an objective of the Food, Drug and Cosmetic Act that safe and efficacious drugs move in interstate commerce without undue hinderance, as that injurious drugs be interdicted. Neither of these objectives, merely at a plaintiff's election, ought to be entrusted to the *exclusive* original jurisdiction of state courts.

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[12] This is especially true where, as here, the federal agency charged with enforcing the Act has given its approval to a drug product in advance of marketing, and the civil tort suit will occasion a *de facto* review of that agency decision by the state court.

The potential impact on the drug industry of adverse state court interpretations of the Food, Drug and Cosmetic Act may easily dwarf the restraints which the Congress intended. In an era of mass tort litigation, the unavoidably delayed ability of this Court to correct state court errors of federal interpretation cannot undo the damage which occurs in the meantime.

CONCLUSION

For the reasons stated in this reply brief, the judgment of the court of appeals should be reversed and the case remanded to the United States Court of Appeals for the Sixth Circuit with directions to affirm the judgment of the district court.

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Respectfully submitted,

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